

*State of the Heart Care***BON SECOURS SOUTH COUNTY HEART CENTER**

May 10, 2000

To: FDA Office of Compliance  
2098 Gaither Road  
Rockville, MD 20850  
Fax: 301-594-4672

Attn: Stewart Crumpler

From: Margaret A. Bench, RN  
Cardiac Rehabilitation Program Coordinator  
Bon Secours South County Heart Center  
1221 Jacaranda Blvd  
Venice, FL 34292

Fax: 941-486-6010

Dear Mr. Crumpler,

Per our conversation on 5/4/00, we are requesting a variance on our telemetry transmitter cables. This is in reference to IEC 60601-1, subclause 56.3(c).

The cost of the conversion would be approximately \$2,400 for parts. This does not include tax, shipping or labor. We have 24 units that this affects. The telemetry units we use have a \$0 fair market value.

Our plan to prevent injury to the patients was instituted on 5/9/00. It is as follows:

1. The telemetry cables have been removed from the patient dressing room.
2. The cables have been placed in the telemetry transmitters.
3. A note has been placed on each unit: "Do not remove cable."
4. A nylon cord has been wrapped around each unit, preventing the patient from removing the cable.
5. The telemetry unit is issued from the Nurse's Desk, and returned prior to the patient leaving the exercise area.
6. When the battery needs to be changed, the staff will remove the nylon cord and replace the battery and cord.

The Board, of Bon Secours South County Heart Center, for which I work met 5/9/00; and feel confident this would protect our patients from electrical injury. Thank you for your time and consideration. I look forward to hearing from you in the near future.

Sincerely,

Margaret A. Bench, RN  
Bon Secours South County Heart Center  
Cardiac Rehab Program Coordinator

00V.1405

VAR 1



Do not remove cable

CE-839

